

# Classroom Discussion Guide on Ethics and Incidental Findings

This guide provides discussion questions and topics based on the Presidential Commission for the Study of Bioethical Issues' report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, to help instructors integrate ethics discussions into a high school or college science course.<sup>1</sup>

## Framing Ethics Discussions in a Science Course

Discussion of these ethical issues does not require previous training in philosophy or ethics. This is true for both the students and the instructor. However, it is a good idea to develop a framework for the discussion to make clear to all participants the goals of the exercise.

Potential frameworks include:

1. The class can frame its discussion around two main considerations:
  - a. Is the test or intervention beneficial in and of itself?
  - b. What are the potential positive or negative consequences of the intervention?
2. The National Institutes of Health Bioethics Curriculum in "Exploring Bioethics" suggests a step-wise framework based on the following questions:
  - a. What is the ethical question?
  - b. What are the relevant facts (scientific and social)?
  - c. Who or what could be affected by the way the question gets resolved?
  - d. What are the relevant ethical considerations?
3. Alternatively, or additionally, the class might engage in a deliberative process to problem solve or generate a policy recommendation. Classroom deliberation encourages students to share competing views and disagree respectfully, with the goal of arriving at consensus about a resolution that seems best given diverse views and perspectives.\*\*

\* National Institutes of Health (NIH). (2009). Exploring Bioethics. Retrieved May 13, 2015 from [http://science.education.nih.gov/supplements/nih9/bioethics/guide/pdf/teachers\\_guide.pdf](http://science.education.nih.gov/supplements/nih9/bioethics/guide/pdf/teachers_guide.pdf)

\*\* McAvoy, P. and D. Hess. (2013). Classroom deliberation in an era of political polarization. *Curriculum Inquiry*, 43(1), 14-47.

<sup>1</sup> Presidential Commission for the Study of Bioethical Issues (PCSB). (2013, December). *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*. Washington, DC: PCSBI. Available at: <http://bioethics.gov/node/3183>.

## Ethics and Incidental Findings

In the report *Anticipate and Communicate*, the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) addressed the ethical challenges that might arise from the discovery of incidental and secondary findings in various contexts.

Incidental findings—typically defined as test results that are outside the original purpose for which the test or procedure was conducted—present a range of ethical, legal, and practical challenges, both for the recipients of test results and the practitioners or researchers who encounter them. The Bioethics Commission considered both *anticipatable incidental findings*—findings that are known to be associated with a particular test or procedure—and *unanticipatable incidental findings*—findings that could not have been anticipated given the current state of scientific knowledge. The Commission also considered *secondary findings*, defined in the report as findings that clinicians or researchers might look for, but are not the primary target of a particular test or procedure.

The Commission considered findings that arise from various modalities, including large-scale genetic sequencing, imaging, and testing of biological specimens, in three different contexts: clinical, research, and direct-to-consumer (DTC). The Commission made a series of overarching recommendations that could be applied to all three contexts, as well as recommendations specific to each context.

### Topic 1: Overarching Considerations

For the purposes of discussion, students should download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission’s website at [www.bioethics.gov](http://www.bioethics.gov) under “Projects”):

*Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, pp. 2-9, 43-52 (“Introduction” and “Overarching Recommendations for Incidental and Secondary Findings”).

Incidental findings...can create a range of practical, legal, and ethical challenges for recipients and practitioners. Discovering an incidental finding can be lifesaving, but it also can lead to uncertainty and distress without any corresponding improvement in health or wellbeing.

Source: Presidential Commission for the Study of Bioethical Issues. (2013, December). *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*. Washington, DC: PCSBI. pp. 2-3.

### Discussion Questions:

1. What are the differences between primary findings, anticipatable incidental findings, unanticipatable incidental findings, and secondary findings? What is an example of each type of finding? Why is it important to distinguish between them?

*Discussion topics might include:*

- *What makes a finding anticipatable or unanticipatable, and what makes a finding secondary*
- *What types of findings might arise in different types of tests (e.g., types of incidental findings that might be seen in an MRI, a genetic test, or in a blood test)*
- *Why it is important to distinguish between these different types of testing, and how do the ethical obligations of clinicians, researchers, and direct-to-consumer providers differ*

2. Why is informed consent about incidental and secondary findings important in clinical, research, and direct-to-consumer contexts?

*Discussion topics might include:*

- *How informing patients, research participants, and DTC consumers about unexpected test results might help them articulate how they feel about getting them back. Some patients might want to know such results, and others might not*
- *It can help clinicians, researchers, and employees at DTC companies plan ahead in case any incidental or secondary findings arise*
- *How informed consent can reinforce respect for persons in this context*
- *It might help clinicians and researchers develop a process that ensures that patients, research participants, and consumers have accessible information to make informed decisions about their health care*

3. What types of actions can help ensure justice and fairness for anyone undergoing a test or a procedure?

*Discussion topics might include:*

- *The importance of having access to adequate information and guidance when making decisions*
- *Having knowledge about and access to the right kinds of tests and subsequent medical care*
- *The impact of knowing or not knowing certain incidental or secondary findings on a person's well-being*

## **Topic 2: Incidental Findings in Different Types of Tests**

For the purposes of discussion, students should download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission's website at [www.bioethics.gov](http://www.bioethics.gov) under "Projects"):

*Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, pp. 9-13, 33-42 ("Introduction" and "Modalities and Probable Incidental and Secondary Findings").

## Discussion Questions

1. Provide an example of a test for each of the following modalities, and an instance in which that test might be used:
  - a. Imaging
  - b. Genetic testing
  - c. Testing of biological specimens
2. For each of the following scenarios, provide an example of an incidental or secondary finding that could arise:
  - a. A patient who has a magnetic resonance imaging scan done after being diagnosed with a concussion
  - b. A college student undergoes a blood draw for a metabolic panel as part of a clinical trial at the local medical school
  - c. A consumer who is curious about his or her genetic predisposition to certain diseases decides to undergo genetic testing through a company that provides genetic testing to consumers via a website
3. How can clinicians, researchers, and direct-to-consumer practitioners using various tests demonstrate respect for their patients, participants, and consumers when handling possible incidental or secondary findings?

*Discussion topics might include:*

- *Reviewing the types of topics that should be part of the informed consent process*
- *Giving patients the choice to know or not to know about incidental or secondary findings*
- *Encouraging patients to ask questions about tests and procedures*
- *Providing accessible information about tests and procedures*

4. What, if any, obligations do clinicians have to examine and report all incidental and secondary findings that might arise in a test or procedure?

*Discussion topics might include:*

- *The ethical obligations clinicians have to their patients (beneficence, non-maleficence)*
- *Whether patients want to know about incidental and secondary findings (respecting patient autonomy)*
- *Whether knowledge about incidental or secondary findings will enhance or hurt a patient's well-being (beneficence, non-maleficence)*
- *The medical, social, and emotional resources a patient has to deal with such findings (justice, beneficence)*

## Case Study: Incidental Findings in a Clinical Context

Students should read the following case. For the purposes of discussion, students should also download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission’s website at [www.bioethics.gov](http://www.bioethics.gov) under “Projects”):

*Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, pp. 53-74 (“Ethical Management of Incidental and Secondary Findings in the Clinical Context”).

In 2004, Carol Krucoff sat for her annual physical. She remembers her primary care doctor performing the routine checks while looking through her medical records. “Let’s get your cholesterol checked,” advised the doctor, “and you’ll need to get a repeat MRI [magnetic resonance imaging test] to monitor that little brain tumor.” Carol was stunned. “What brain tumor?” she stammered. The doctor explained to Carol that a previous MRI, conducted when Carol had been in a coma, revealed an abnormality.

About six months earlier, Carol had participated in a marathon and had over-hydrated, inadvertently consuming too much water. In the last mile, she began to feel dizzy as her sodium level fell dangerously low. Just after crossing the finish line, Carol had a hyponatremia-induced seizure and was air lifted for medical treatment. She awoke from a coma four days later in an intensive care unit. Carol had only a vague recollection of the doctors telling her that they had performed an MRI and had incidentally discovered a small acoustic neuroma. At the time, Carol had not thought of this incidental finding as potentially dangerous; her trauma clinicians had never used the phrase “brain tumor.”

After Carol’s 2004 annual checkup, she went online to learn more about her acoustic neuroma. Carol researched her options: she could have a surgical removal, undergo radiation therapy, or simply watch and wait. After much consideration, Carol chose to monitor through routine observation. Carol has been watching for nine years—and watching required commitment and nine MRIs. Now, says Carol, “I try to completely forget that I even have this little brain tumor. Had I not learned about it as an incidental finding, I would have been blissfully ignorant.” But Carol is not certain that blissful ignorance would have been her preference. “If the question [is], do I wish they hadn’t told me, my answer is definitely no. If they know, I want to know.”

Source: Krucoff, C., Recipient of a finding incidental to clinical care. (2013). Incidental Findings in the Clinic. Presentation to the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission), April 30. Retrieved from <http://bioethics.gov/node/1619>.

## Discussion Questions

1. What are the ethical issues in this scenario?

*Discussion topics might include:*

- *How Carol came to learn about her brain tumor*
- *The avenues Carol had to exercise autonomy*
- *Beneficence and non-maleficence*
- *Communication between the clinicians and the patient*

2. After learning about an incidental finding, how can patients exercise their autonomy?

*Discussion topics might include:*

- *Asking questions about relevant information*
- *Seeking a second opinion with a specialist*
- *Understanding all options, including intervention and monitoring*
- *Considering whether and how to inform others, including family members who might also be affected by genomic incidental findings*

3. What factors should clinicians consider when deciding how to communicate incidental or secondary findings?

*Discussion topics might include:*

- *When and how to communicate results*
- *What information to communicate, and what information to leave out*
- *How to ensure that patients have the information needed to make an informed decision*
- *How clinicians can best assist patients in determining an appropriate plan of action*
- *How to minimize distress and anxiety*

"We have a bias toward doing something as opposed to doing nothing. It feels right even if it's wrong, which in many cases it surely is. And our patients almost uniformly want us to do something. Both doctor and patient are enthralled in this overwhelming medical imperative to act. Remaining still—old-fashioned watchful waiting—requires a fortitude that few doctors are able to muster."

Ofri, D., Associate Professor, New York University School of Medicine, Editor-In-Chief, *Bellevue Literary Review*. (2013). *Incidental Findings in the Clinic*. Presentation to the Bioethics Commission, April 30. Retrieved from <http://bioethics.gov/node/1619>.

## Case Study: Incidental Findings in a Research Context

Students should read the following case. For the purposes of discussion, students should download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission's website at [www.bioethics.gov](http://www.bioethics.gov) under "Projects"):

*Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, pp. 75-93 ("Ethical Management of Incidental and Secondary Findings in the Research Context").

Sarah Hilgenberg will never forget the summer of 2002. She had finished her second year as a clinical researcher in neurology at Massachusetts General Hospital and was about to begin her first year at Stanford University School of Medicine. Young and healthy, Sarah looked forward to her future. As part of her medical school orientation, Sarah spent four days camping in the Sierra Nevada Mountains with her new classmates. A few weeks later, Sarah received an email from one of the camping leaders, a graduate student studying functional magnetic resonance imaging (fMRI). Two research participants had canceled their sessions for an upcoming research study and the camping leader wondered if any group members would be interested in having their brain scanned while performing a memory task. Sarah volunteered to help. The next day, Sarah went to the campus imaging center and participated in the fMRI study.

Later that day, her phone rang. The fMRI researchers had found an anomaly on her scans. Sarah rushed to the emergency room for further evaluation. Ultimately, the doctors concluded that Sarah had an arteriovenous malformation, an abnormal connection between arteries and veins in her brain. They recommended that she undergo removal of the mass. Sarah chose to stay in medical school during this time. Pursuing treatment of the incidental finding on her fMRI scan gave Sarah a new perspective: that of a patient. She remembers, “I was learning firsthand the material taught in class, the vulnerability of the body and, in particular, of my brain.” Fortunately, Sarah’s surgery was successful and she has recovered well. She notes: “I believe I’ve had the best outcome I probably could have had.... In 2011, my husband and I had a daughter...who is the most special person in our lives. I was so unbelievably thankful that I no longer had [this malformation] in my brain during childbirth as I learned this is a common time for one to bleed.”

Sarah is now a pediatric hospitalist, dealing occasionally with incidental findings as a practitioner rather than as a patient. But she will undoubtedly remember her time as a patient and the incidental finding that changed her life.

Source: Hilgenberg, S., Recipient of a finding incidental to research. (2013). Incidental Findings in Research. Presentation to the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission), April 30. Retrieved from <http://bioethics.gov/node/1617>

## Discussion Questions

1. If the researchers had not called Sarah about the anomaly on her scans, should they have been held responsible if this finding negatively impacted Sarah’s health? Why or why not?

*Discussion topics might include:*

- *What other actions could have resulted from the researchers sharing, or not sharing, the findings*



- *Are researchers ethically obligated to share such information with study participants, and how this obligation could change if the study is being conducted by a clinician-researcher*
  - *If another health care worker had interpreted the fMRI results differently:*
    - *The results were considered normal*
    - *The health care worker advised her to adopt “watchful waiting,” or monitoring the finding periodically*
  - *If Sarah might have had any other opportunities to learn about this finding*
2. What ethical features might suggest that researchers have or do not have an ethical obligation to report incidental findings to study participants?

*Discussion topics might include:*

- *How the ethical obligations of researchers differ from clinicians*
  - *What qualifications that researchers might or might not have to properly explain incidental findings to study participants*
  - *How disclosing and handling incidental findings can impact the primary goals of the study*
  - *What other opportunities study participants might or might not have to find out about possible incidental findings*
3. If Sarah had participated in this study at a rural community hospital, without the resources and state-of-the-art clinical care available at Stanford, how would it have impacted the researchers' obligation to share, or not to share, Sarah's incidental finding? Can investigators ethically assign researchers without the expertise to detect and interpret anomalies, in order to purposefully avoid discovering incidental findings?

*Discussion topics might include:*

- *How Sarah being at Stanford – a top research institution that attracts highly qualified researchers and clinicians — impacted her ability to quickly receive a diagnosis and follow-up care*
- *Whether investigators can ethically “blind” themselves to information about incidental findings, by assigning non-clinicians to read research scans*
- *Whether researchers can be ethically obligated to share incidental findings for which there are limited consultation or treatment options nearby*
- *How researchers at institutions with fewer resources can feasibly manage follow-up care for incidental findings*
- *The potential added cost of a policy or regulation that mandates returning incidental findings, especially on institutions with limited resources*



## Case Study: Incidental Findings in a Direct-to-Consumer Context

Students should read the following case. For the purposes of discussion, students should download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission’s website at [www.bioethics.gov](http://www.bioethics.gov) under “Projects”):

*Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, pp. 95-110 (“Ethical Management of Incidental and Secondary Findings in the Direct-to-Consumer Context”).

Thirty-four year old Jackie,\* an employee of a biomedical research laboratory, was curious about her predisposition to various diseases so signed up for a medical risk report from a direct-to-consumer genetic testing company. She knew that cancer, alcoholism, and bipolar disorder ran in the family. Jackie and her brother Alex\* wanted to know more, so the siblings sent saliva samples into the company and agreed to go over their results together. Jackie and Alex read through their reports online, and were not surprised by any of the results. At the end of the report, the system prompted them to opt in to an additional service that could link users to close relatives who had also submitted genetic information. Jackie and Alex both opted in to the service— and learned of a result that took them by surprise. The results stated that Alex and Jackie shared only a quarter of their DNA, not half, which is what siblings share. Jackie posted this odd finding on a forum for questions and discussion about the company’s results.

The community of users told Jackie that the system had detected that Jackie and Alex shared one-quarter of their DNA. While full siblings share 50 percent of their DNA, more distant relationships, such as uncle and niece, grandfather and granddaughter, or half siblings share only 25 percent of their DNA. This meant that Alex and Jackie could be uncle and niece, grandfather and granddaughter, or half siblings. Jackie and Alex were confused and distressed by the news. Jackie asked their mother about the result, and her mother admitted to an affair that resulted in Jackie’s birth. Jackie described the experience as surreal, saying, “I looked in the mirror and thought, who is this person?”

The online company’s policy was to inform its users that its genetic testing service can reveal misattributed paternity and other surprises about biological relationships that could result in strong emotions or change one’s worldview. Despite being warned about this risk, Jackie was shocked to discover this anticipatable incidental finding.

\*Names have been changed.

Sources: Engber, D. (2013, May 21). Who’s your Daddy? The perils of personal genomics. Slate. Retrieved from [http://www.slate.com/articles/health\\_and\\_science/science/2013/05/paternity\\_testing\\_personal\\_genomics\\_companies\\_will\\_reveal\\_dna\\_secrets.html](http://www.slate.com/articles/health_and_science/science/2013/05/paternity_testing_personal_genomics_companies_will_reveal_dna_secrets.html); 23andMe. (n.d.). Terms of Service [Webpage]. Retrieved from <https://www.23andme.com/about/tos/>.

## Discussion Questions

1. What are the ethical dimensions in this scenario?

*Discussion topics might include:*

- *What Jackie and Alex intended to find out through their DNA testing*
- *What the company disclosed about potential test results*

2. What, if anything, could the genetic testing company have done differently to prepare users for potentially shocking test results?

*Discussion topics might include:*

- *How the informed consent process can ensure that consumers are aware of the impact of certain test results*
- *Whether consumers want to know certain types of information*
- *Whether there were any additional steps that 23andMe could have taken to ensure that consumers such as Jackie and Alex were aware of the implications of paternity results*
- *Whether 23andMe, as a direct-to-consumer company, should be disclosing such sensitive information*

3. What are the ethical duties, if any, for online testing companies to their customers?

*Discussion topics might include:*

- *Ensuring that consumers have the information needed to make an informed decision*
- *Ensuring the safety and accuracy of certain tests and procedures*
- *Transparency regarding the potential impact of results garnered through direct-to-consumer tests and procedures*
- *Participating in the development of industry-wide best practices regarding the handling of incidental and secondary findings*

DTC testing can offer individuals a means through which they can exercise self determination, including by providing increased access, reduced cost, and greater confidentiality of health information. But the benefits of DTC services are contingent upon the quality of the testing and analyses, and the informed and voluntary nature of the transaction. To enable consumers to make responsible and informed choices regarding DTC testing, consumers must be told what these procedures entail, including the possibility of incidental and secondary findings. Information provided before selecting a DTC procedure can assist consumers in deciding what services are worth pursuing.

Source: Presidential Commission for the Study of Bioethical Issues. (2013, December). *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*. Washington, DC: PCSBI. p. 103.